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EXAMINER
JARRELL, NOBLE E

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In re Application of	:
Jones et al	:
Serial No.: 10/541,657	:DECISION ON PETITION
Filed: 3 March 2006	:
Attorney Docket No.: 20750-0007US1	:

This letter is in response to the Petition filed under 37 C.F.R. 1.144 and 1.181 filed on 13 August 2010 and the Petition filed under 37 CFR 1.182 to request expedited review.

BACKGROUND

A summary of the prosecution history may be found in the following two petition decisions:

(i) Petition decision mailed 3 March 2010, which withdrew finality of the Office action mailed 17 December 2009.

(ii) Petition decision dated 4 December 2009 granting in part applicants request for reconsideration of the restriction requirement.

On 13 May 2010, the examiner mailed a final Office action, in which claims 4, 5, 62-66, 79-85, 87-92 and 100 were withdrawn from consideration. The restriction was made final. Claims 1-3, 12-14, 16-61, 73, 74 and 78 were rejected under 35 U.S.C. 112, first paragraph for lack of enablement. No claims were rejected under prior art.

An advisory action was mailed 14 October 2010.

On 13 August 2010, applicants filed the petitions under consideration.

DISCUSSION

The petition and file history have been carefully considered.

This application was filed as a national stage application in compliance with under 35 U.S.C. 371 and as such is subject to PCT unity of invention practice.

Applicants wish to have the restriction requirement withdrawn. Because this application is filed as a national stage application in compliance with 35 USC 371, at each step of prosecution, the examiner should re-assess unity of invention with regard to the claims as pending and the state of the prior art.

It is noted that the examiner has placed the process claims in groups as follows:

XV. A method for controlling or decreasing weight gain, according to Claim 82.

XVI. A method of modulating a RUP3 receptor, according to claim 83.

XVII. A method of modulating a RUP3 receptor, according to claim 84, 85, 87-92.

XVIII. A method of producing a pharmaceutical composition, according to claim 100.

In the restriction requirement, Claims 82- 85, 87-92 were placed into three separate groups. This is unwarranted. All of Claims 82- 85, 87-92 require the technical feature of contacting the RUP3 receptor with the compound of claim 1. Here, Applicants are claiming a product, a process of making the product (claim 100) and a single process of using the product (claims 82-85 and 87-92.)

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

In this application, the examiner maintained lack of unity in the Final Office action, even though there was no prior art rejection on elected product claims. This was incorrect. If the claimed product is free of the prior art, the examiner should be rejoining the first method of making and the first method of using the claimed product, per 37 CFR 1.475.

It is noted that in the original restriction requirement, the product claims 1-78 had been placed into 13 groups depending upon the variables of the Markush members. This is not consistent with ISPE Guidelines.

> "10.17 Rule 13.2 also governs the situation involving a single claim that defines alternatives (chemical or non-chemical), the so-called "Markush practice." In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, is considered met when the alternatives are of a similar nature.
>
> (a) When the Markush grouping is for alternatives of chemical compounds, they are regarded as being of a similar nature where the following criteria are fulfilled:
>
> (A) all alternatives have a common property or activity, and
>
> (B)(1) a common structure is present, that is, a significant structural element is shared by all of the alternatives, or
>
> (B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains."

Here, all the compounds have a common property or activity as agonists of the RUP3 receptor. Applicant's arguments on pages 11-14 of this petition are convincing concerning the significant structural element shared by all the alternatives. The examiner has provided no prior art to demonstrate that the claims, as amended, fail to make a contribution over the prior art. For

these reasons, the restriction between Groups I-XIII is unwarranted and has been replaced by an election of species requirement amongst the alternatives. Moreover, it is noted that MPEP 803.02 sets forth guidance concerning the examination of examination required for Markush claims:

> In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits. An examiner should set forth a requirement for election of a single disclosed species in a Markush-type claim using form paragraph 8.01 when claims limited to species are present or using form paragraph 8.02 when no species claims are present. See MPEP § 808.01(a) and § 809.02(a). Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

DECISION

The petitions filed under 1.144, 1.181 and 1.182 are **GRANTED** for the reasons set forth above.

The finality of the Office action mailed 13 May 2010 has been withdrawn.

The amendment filed on 13 August 2010 will be entered.

The restriction requirement between the alternatives of the Markush claim, Groups I-XIII, has been withdrawn and replaced by an election of species requirement. If the elected species is allowable, the examiner will follow the practice in MPEP 803.02 and examine a second and subsequent species, until the patentability of the Markush claims is determined.

The restriction requirement between groups XV, XVI and XVII, directed to process of using the product, has been withdrawn. Claims 82- 85, 87-92 are rejoined for examination.

The restriction requirement between the product and the first method of using the product (rejoined groups XV, XVI and XVII, Claims 82- 85, 87-92) and the first method of making the product (Group XVIII, claim 100) has been withdrawn, in view of the fact that there is no prior art cited on the products.

The application will be forwarded to the examiner for preparation of an Office action consistent with this decision, and following the Markush examination guidelines in MPEP 803.02.

The supervisory patent examiner is expected to personally check on the pendency of this application which is up for the third or subsequent Office action with a view to finally concluding its prosecution. See MPEP 707.02.

Should there be any questions about this decision, please contact Quality Assurance Specialist Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

George C. Elliott, for

Remy Yucel
Director, Technology Center 1600